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Confidential

K040201

Burr Hole Valve and Shunt System
510(k) SUMMARY

Submitter's name and address:

Integra NeuroSciences Implants SA
2905 Route des Dolines
06921 Sophia Antipolis Cedex, France

Contact person and telephone number:

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Date summary was prepared:

January 20, 2004

Name of the device:

Proprietary Name:	Burr Hole Valve and Shunt System
Common Name:	Hydrocephalus Shunt Systems and Components
Classification Name:	Central Nervous System Shunt and Components JXG

Substantial Equivalence:

The Burr Hole Valve and Shunt System is substantially equivalent in function and intended use to the currently marketed unmodified Burr Hole and Shunt System and the unmodified Burr Hole™ Valve and Shunt System which has been cleared to market under Premarket Notification 510(k) K970578.

Intended use:

The Burr Hole Valve and Shunt System is indicated for use in the treatment of patients with hydrocephalus. The Burr Hole Valve is a component of a system designed to shunt cerebrospinal fluid from the ventricles of the brain to an appropriate drainage site, such as the atrium of the heart or the peritoneal cavity.

Device Description:

The Integra NeuroSciences Burr Hole Valve incorporates a membrane valve with integral connectors and domed reservoir to fit into a formal burr hole. It is used in treatment of patients with hydrocephalus when shunting cerebrospinal fluid (CSF) from ventricles of the brain. The Burr Hole design includes a flat silicone membrane, which provides resistance to CSF flow. The silicone membrane seats on a conical polypropylene base. This base is int4egral to a rigid outlet port. The design allows for accurate and precise regulation of CSF flow due to its structural integrity. The flat silicone membrane also prevents retrograde flow of CSF.

The Burr Hole valve is available in two sizes designed to fit a 12mm or 16mm formal burr hole. Both sizes are available in three (3) pressure/flow characteristics ranges: low, medium, and high.

Safety

The Burr Hole Valve and Shunt Systems are provided sterile and non-pyrogenic. The Burr Hole Valve and Shunt Systems have been tested for pressure/flow, leakage, catheter elongation and bending, markings visual inspection, pull testing and radiopacity.

Conclusion

The modified Burr Hole Valve and Shunt System is substantially equivalent to the unmodified Burr Hole Valve and Shunt System. The modifications do not affect the intended use, the fundamental scientific technology of the device, and do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Integra NeuroSciences Implants SA
c/o Ms. Judith E. O'Grady
Senior Vice President Regulatory,
Quality and Clinical Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K040201
Trade/Device Name: Burr Hole Valve and Shunt System
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: January 27, 2004
Received: January 29, 2004

Dear Ms. O'Grady::

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040201

Device Name: Burr Hole Valve and Shunt System

Indications For Use:

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Prescription Use _X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040201